Message

From: Striegel, Wiebke [Striegel.Wiebke@epa.gov]
Sent: 9/25/2017 6:38:50 PM
To: McNally, Robert [Mcnally.Robert@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Carlisle, Sharon [Carlisle.Sharon@epa.gov]
CC: Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]
Subject: FW: FDA/EPA Comms Touch Base about Mosquito Final Guidance

Importance: High

Hello,

I just received the below request regarding Oxitec and #236 from Isabella in FEAD. I am handing this off to Elizabeth as the primary contact for Oxitec (unless instructed otherwise) and also loop in management. It looks like the questions came from FDA.

I am not sure why this request went through FEAD, but I'd suggest looping in Isabella in case she needs to track the action in the system.

With kind regards,

Wiebke

From: Bennett, Isabella
Sent: Monday, September 25, 2017 2:28 PM
To: Striegel, Wiebke <Striegel.Wiebke@epa.gov>
Subject: FDA/EPA Comms Touch Base about Mosquito Final Guidance
Importance: High

Good afternoon Wiebke!

Just received this request from OCSPP IO about Oxitec GE mosquitos. Specific details in the below chain, but in summery they are asking us to respond to these three questions and come up with just a few (if there are any) additional questions we could receive, and then answer those as well.

I'm asking now for when they would like these by so I'll get back to you with that.

What further regulation will the sponsor have to go through to conduct field trials in jurisdictions within the US or to get a commercial approval for the mosquitoes? Will EPA rely on the data the sponsor already provided to the FDA? How long will the process take?

Do you have any applications/permits/whatever the correct terminology is from Oxitec in house that you are currently reviewing?

Do you have comment on FDA's guidance? Will this delay the approval/permitting of Oxitec's GE mosquitoes to Hurricane-stricken areas?

From: Strauss, Linda
Sent: Monday, September 25, 2017 1:08 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>; Sisco, Debby <Sisco.Debby@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Lantz, Tracy <Lantz.Tracy@epa.gov>
Subject: FW: FDA/EPA Comms Touch Base about Mosquito Final Guidance

OPP, can we get answers to these Q's suggested by FDA? Are there other Q's we think we'll get? Thank you.
Linda

From: Putnam, Juli [mailto:JuliAnn.Putnam@fda.hhs.gov]
Sent: Monday, September 25, 2017 1:02 PM
To: Strauss, Linda <Strauss.Linda@epa.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: FDA/EPA Comms Touch Base about Mosquito Final Guidance

Hi Linda,
Thanks for giving me a ring. We will check in with our Office of Policy on the current status of the final guidance and report back.

We will also share our list serv email and responsive QAs soon. However, please note these are Q&As from FDA perspective. EPA will likely get questions that we don't address in our Q&As because we'll no longer have jurisdiction over Oxitec's GE mosquito (and any other mosquitoes that have population suppression claims), so it may make sense for EPA to develop a few separate responsive QAs along a parallel track and then we can share with each other. I think the questions you are most likely to get asked are:

Ex. 5 - Deliberative Process

We will absolutely wait until the FR Notice displays before we send out the list serv email.

We will keep you posted on timing.
Thank you!
Best,
Juli

From: Strauss, Linda [mailto:Strauss.Linda@epa.gov]
Sent: Monday, September 25, 2017 11:53 AM
To: Putnam, Juli
Cc: Norris, Anne
Subject: RE: FDA/EPA Comms Touch Base about Mosquito Final Guidance

Hi Juli, good to chat with you this morning.

Sounds like we have provided comments, and FDA is now addressing them. Not sure if FDA is still awaiting comments from USDA and USTR.

I think the best plan forward is for us to review the draft (embargoed) FDA Q's and A's and listserv. We might add some Q's and A's depending on what you already have. When ready, we can push out the FDA listserv to our audiences and post the final guidance on our web.

Does that work for you? Also, were you wait until the FR posts to send the listserv?

Thanks! Linda
202-564-0797

From: Norris, Anne [mailto:Anne.Norris@fda.hhs.gov]
Sent: Monday, September 25, 2017 9:38 AM
To: Strauss, Linda <Strauss.Linda@epa.gov>; Valentine, Julia <Valentine.Julia@epa.gov>; StClair, Christie <StClair.Christie@epa.gov>; Daguillard, Robert <Daguillard.Robert@epa.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Subject: FDA/EPA Comms Touch Base about Mosquito Final Guidance

Hi Linda,

Do you have any availability this afternoon or tomorrow morning to discuss communications planning around the release of the final Guidance for Industry #236?

We just want to share our thinking, hear your input, and make sure we're on the same page.

Thanks,
Anne

Anne Norris
Health Communications Specialist

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